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| 09/782,594 | 02/12/2001 | John R. Bianchi | RTI- 112R | 9490 |

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| EXAMINER |
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PREBILIC, PAUL B

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3738

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05/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/782,594

Applicant(s)

BIANCHI ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-34, 61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-34, 61 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 26, 2007 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26 and 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 79 of copending Application No. 09/941,154. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claim 79 is read on by what is set forth in the claims of this application such claim 79 would be "anticipated"

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thereby. For this reason, the claims are considered obvious in view of claim 79; see *In re Goodman, supra*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis (US 5,147,367), or in the alternative, under 35 U.S.C. 103(a) as being obvious over Ellis (US 5,147,367) alone. Ellis anticipates the claim language where the bone pieces or bone portions as claimed are the bone portions of the same patient grafted onto the bones they were separated from to form a graft in Ellis; see the figures, the abstract and column 5, lines 12-56. "Graft" is denoted as "anything inserted into something else so

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as to become an integral part of the latter"; Stedman's Medical Dictionary, 23rd Edition, p. 599. "Allograft" is a homograft (i.e. from the same species) that is allogenic (i.e. genetically distinct) to the recipient; see Merriam-Webster OnLine at www.m-w.com/cgi-bin/dictionary?book+=Dictionary&va=allograft. Since the bone of Ellis is capable of being used as a bone graft unit upon the death of the individual, it is considered an allograft bone portion with respect to another human being to the extent that this language can be given patentable weight. The site of source of the material is relative to how it can be used and is not indicative of the material itself because the pieces of Ellis are allogenic with respect to another human being. For these reasons, the separated bone pieces are grafts and allografts when these terms are given their broadest reasonable interpretation. The new claim language requiring "machined" bone portions is not structurally distinguishing from that disclosed by Ellis because it does not require any particular structure in the device; see MPEP 2113 that is incorporated herein by reference.

Alternatively, Ellis could be interpreted as not meeting the claim language because one may interpret "machined" as implying a particular structure not disclosed by Ellis. However, since "machined" at most only may imply a slight difference from that of Ellis, the Examiner asserts that Ellis renders the claim language at least clearly obvious.

With regard to claim 32, the pins of Ellis are cortical bone pins because they are for cortical bone the same way a "bone screw" is for bone even though it can be made of a metal.

Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ochoa et al (US 5,716,358) in view of Ellis (US 5,147,367). Ochoa discloses bone portions or pieces grafted back onto bones they were separated from but fails to clearly disclose the use of a plurality of pins as now claimed; see Figures 4 and 5 as well as column 6, line 57 to column 8, line 47. However, Ellis teaches that it was known to use a plurality of pins to attach bone pieces together; see *supra*. Therefore, it is the Examiner's position that it would have been obvious to use a plurality of pins in the Ochoa invention in order to better secure the pieces together and for the same reasons that Ellis uses the same.

Claims 26-34 and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels et al (EP 0517030) in view of Coates et al (US 5,989,289). Siebels discloses an assembled bone implant made by assembling separate bone implant pieces together to form an implant by aligning bores of adjacent pieces. Next, Siebels introduces pins into the aligned bones to hold the implant pieces together; see Figures 1 and 2 and page 8 of the translation, first full paragraph and page 9 of the translation. Siebels also discloses that "the hollow space is filled with bone material or bone cement for the purpose of a radial anchoring of the ring"; see page 5 of the translation. Also, on page 11 of the translation, Siebels discloses that "extraneous bone material, or the patient's own bone material" can be used to fill the cavity. However, Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6).

Coates, however, teaches that it was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61. Therefore, it is the Examiner's position that it would have been obvious to make the disks and pins of the Siebels implant out of cortical bone for the same reasons the Coates teaches doing the same.

Regarding claims 28-30, the spacers of Coates can have osteogenic material of demineralized bone and/or allograft bone applied to them such that the pin(s) of Siebels, which would be made into bone because of the teachings of Coates, would also have these materials applied to them. Any segment thereof could be said to be made of cortical bone.

Response to Arguments

Applicants' arguments filed February 26, 2007 have been fully considered but they are not persuasive in all cases.

Applicants failed to traverse the double patenting rejection and stated that they will address the provisional rejection once the application is otherwise allowable.

Applicants traverse the rejection utilizing Ellis by arguing that Ellis does not disclose a "graft" because the bone pieces are not supposed utilized by the Examiner in a way that is "understood by the art." Rather, the Applicant understands the term as meaning that the material must be from a different site or source. This has not been found persuasive because this argument is not based upon a structural difference, but rather, relies solely on where the material is obtained instead of a structural difference.

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In other words, the argument that the term "graft" is not used to describe his material is not persuasive. Furthermore, the fact that the Ellis does disclose that the material is not from a different site or source is not based upon the structure of the device, but rather, it is based upon the source of the material. Since the source of the material is not limiting in the context of the present claims, the argument is considered wholly unpersuasive.

Furthermore, the Examiner maintains that the broader definition applied is appropriate because there is no special definition for this term in the specification and because the broader definition is the broadest reasonable one available; the Examiner has included a copy of the definition from Stedman's Medical Dictionary utilized in the previous Office action.

Next, Applicants argue that the term "allograft" inherently means that the tissue has been chemically and physically processed into a non-living material that is said to be suitable for implantation. Although the art does process some allogenic materials for implantation, it is not inherent that all allografts are processed because there are clearly some allografts that are not processed; see, for example, US-20030077825 in paragraph [0024], US-20030036800 in paragraph [0007], and US-6,398,786 on column 1, lines 39-44 (see MPEP 2112.01 that is incorporated herein by reference). For this reason, the Examiner asserts that "allograft" merely indicates where the tissue is obtained and how it is intended to be used and not on any clear structural feature of the material. Moreover, the whole transplant industry relies on living tissue grafts to provide

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the recipient with living tissue grafts. For these reasons, the rejections have been maintained.

On page 8 of the February 26, 2007 response, the Applicants argue that Ellis does not disclose an assembled bone graft. However, it is noted that this terminology is taken from the preamble and that the preamble is not incorporated into the body of the claims. For this reason, the preamble is merely considered to be a statement of intended use and it does not structurally limit the claim language.

On page 10 of the response, the Applicants argue that Ellis does not disclose machined portions of bone. However, the Examiner asserts that this language is not clearly limiting because even a kick on the bone would constitute a machining. Furthermore, since the bone joined by a fastener, it is machined to accommodate the fastener to the extent that this term can be given patentable weight.

With regard to the rejections utilizing Siebels and Coates, the Applicants' arguments follow the line of reasoning that it would not have been obvious to combine Siebels with Coates because Siebels wants easy assembly and Coates says that implants made of bone have been difficult to make.

In response, the Examiner asserts that Siebels desires easily assembleable disks that enable the surgeon to quickly assemble pre-manufactured disks into an appropriately sized implant. Coates, on the other hand, states that implants made with bone have had problems due primarily to their shapes and cancellous bone make-up. Coates discloses one example of a bone dowel that was not stable due to shape and cancellous bone make-up see the discussion of Cloward on column 3. Assembly of the

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implant pieces was not an issue. Coates solved the problems of the prior art by making the implant primarily of cortical bone and making the implant into a rectangular shape with vertebra engaging teeth and ridges to prevent migration. For this reason, the Examiner asserts that Coates is discussing an entirely different issue than that of Siebels. For this reason, the Applicants' line of reasoning is not persuasive.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
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